k120813

510(k) Summary

DEC 07 2012

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirement of SMDA and 21 CFR 807.92.

1.0 submitter's information

Name: Andon Medical Co., Ltd.

Address: No.26 Hangn Yu Road, Tianjin Airport Economic Area, Tianjin, P.R. China

Phone number: 86-22-8761 2426

Fax number: 86-22-6052 6162

Contact: Yi Liu

Date of Application: 03/15/2012

2.0 Device information

Trade name: iHealth BG3 Smart Gluco-Monitoring System

Common name: Blood Glucose Monitoring System

Classification name: Blood Glucose Monitoring System

3.0 Classification

Production code: NBW- Blood Glucose Monitoring System.

Regulation number: 862.1345

Classification: II

Panel: Clinical Chemistry

4.0 Predicate device information

Manufacturer: Andon Medical Co., Ltd.

Device: AG-608N Single Blood Glucose Monitoring System

510(k) number: k110017

5.0 Device description

iHealth BG3 Smart Gluco-Monitoring System consist of blood glucose meter, single use test strips, sterile lancets, lancing device and the control solutions.

The new device iHealth BG3 Smart Gluco-Monitoring System is based on an electrochemical biosensor technology (electrochemical) and the principle of capillary action. Capillary action at the end of the test strip draws the blood into the action chamber and the blood glucose result is displayed in 5 seconds. The control solution available is used to test the performance of the device. It uses the same technological characteristics for testing with its predicate device.

The appearance of iHealth BG3 meter is different from the predicate device. More over, the new device iHealth BG3 Smart Gluco-Monitoring System can not display the test results itself, it has to connect an iPhone or iPod touch to complete its function.

6.0 Intended use

iHealth BG3 Smart Gluco-Monitoring System is intended to be used for:

- quantitative measurement of glucose in fresh capillary whole blood samples drawn from the fingertip, palm, forearm, upper arm, calf or thigh
- single person measurement only and should not be shared
- self-testing outside the body (in vitro diagnostic use) by people with diabetes at home as an aid to monitor the effectiveness of diabetes control

The iHealth BG3 Smart Gluco-Monitoring System should not be used for the diagnosis of or screening for diabetes, or for neonatal use.

Alternative Site Testing (AST) should be done only during steady state times when glucose levels are not changing rapidly.

The AGS1000I test strips are intended for use with the iHealth BG3 meter to quantitatively measure glucose in fresh capillary whole blood samples drawn from the fingertips, palm, forearm, upper arm, calf or thigh using the iHealthBG3 meter

7.0 Summary comparing technological characteristics with predicate device

CHARACTERISTICS	NEW DEVICE: iHealth BG3 Smart Gluco-Monitoring System	PREDICATE: AG-608N Single Blood Glucose Monitoring System (K110017)
Detection Method	Amperometry	Amperometry
Enzyme	Glucose Oxidase	Glucose Oxidase
Type of Meter	Biosensor (Electrode)	Biosensor (Electrode)
Sample Source	Capillary whole blood from AST(Alternative site testing) and finger	Capillary whole blood from AST(Alternative site testing) and finger
Sample Application	Blood sample is placed directly to the test strip after finger or AST is lanced.	Blood sample is placed directly to the test strip after finger or AST is lanced.
Hematocrit Range	20-60%	20-60%
Operating Temperature Range	10℃～35℃(50°-95°F)	10℃～40℃(50°-104°F)
Dimensions	102mm×58mm ×22mm	52mmx 92mmx 21mm
Display	Connect to iPone or iPod touch to display measurement results	LCD
Result Presentation	mg/dL or mmol/L	mg/dL or mmol/L
Memory Capabilities	10000 times with time and date displaying	500 times with time and date displaying
Test Start	Automatic	Automatic
Test Time	5 second	5 second
Power Source	DC 3.3V (Powered by iOS device connected to the meter)	DC 3V (CR2032)
Battery Life	N/A	Approx. 500 normal tests
Measurement Range	20mg/dL-600mg/dL (1.1mmol/L~33.3mmol/L)	20mg/dL-600mg/dL (1.1mmol/L~33.3mmol/L)
Qualified Test Strip	AGS-1000I Test Strip	AGS-1000N Test Strip
Sample Volume	Minimum 0.7 micro liter	Minimum 0.7 micro liter
Other function	N/A	USB function. Voice function

8.0 Performance summary

iHealth BG3 Smart Gluco-Monitoring System conforms to the following standards:

- ISO 15197: In vitro diagnostic test systems- Requirements for blood-glucose monitoring systems for self-testing in managing diabetes mellitus.

Non-clinical test and the clinical test are done according to the above standard.

9.0 Comparison to the predict device and the conclusion

iHealth BG3 Smart Gluco-Monitoring System is similar with the predicate device AG-608N Single blood pressure monitor, the two devices are both for single people use, they use the same test strip, and can test the blood glucose at the alternative site. The hematocrit range, the altitude and the use function are all the same. The appearance of the two device is different, and iHealth BG3 meter does not have a LCD itself, it must be connected to an iPone or iPod touch to display measurement results. More over, the memory capability of the new device is changed, and the new device neither has the USB function nor Voice function.

However, the test in this submission provides demonstration that these small differences do not raise any new questions of safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-002

Andon Medical Co., Ltd.
c/o Yi Liu
No.26 Hang Yu Road
Tianjin, P.R. China 300381

December 7, 2012

Re: k120813
Trade/Device Name: iHealth BG3 Smart Gluco-Monitoring System
Regulation Number: 21 CFR §862.1345
Regulation Name: Glucose test system
Regulatory Class: Class II
Product Code: NBW, CGA, JQP
Dated: November 26, 2012
Received: November 29, 2012

Dear Mr. Yi Liu:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostics and Radiological Health at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Yung W. Chan

for Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology Devices
In Vitro Diagnostics and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indication for Use

510(k) Number (if known): K120813

Device Name: iHealth BG3 Smart Gluco-Monitoring System

Indication For Use:

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Prescription Use √	And/Or	Over the Counter Use √
(21 CFR Part 801 Subpart D)		(21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K120813